Remarks

The Examiner's withdrawal of the rejection of claims 1-11 under 35 U.S.C. first paragraph (enablement), made in paragraph 9 of the office action mailed on December 22, 2003 is appreciated.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

Claims 1 and 3-11 were rejected under 35 U.S.C. §112 for not being enabled. Applicants respectfully draw the Examiner's attention to the withdrawal of the rejection of claims 1-11 under 35 U.S.C. first paragraph as stated above. The rejection on paragraph 9 of the office action mailed on December 22, 2003 was an enablement rejection. Although claim 1 was subsequently amended, claim 1 was amended to include limitations from claims 6 and 7. It is therefore not clear to Applicants how the Examiner can withdraw an enablement rejection of claims 1-11 and then make an enablement rejection of the same set of claims. Clarification is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph, written description

Claims 1 and 3-11 were rejected under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. Applicants respectfully traverse this rejection.

The Legal Standard

The general standard for the written description requirement is that "a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably

conclude that the inventor had possession of the claimed invention." *See* M.P.E.P. § 2163(I). All that is required is that the specification provides sufficient description to **reasonably** convey to those skilled in the art that, as of the filing date sought, that the inventor was in possession of the claimed invention. *Union Oil of California v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000); *Vas Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant may show possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Analysis

From the discussion in the specification, it is clear that Applicants were in possession of the claimed subject matter. The claims define a vaccine composition for inducing an immune response to a pathogen comprising a nucleic acid encoding an antigen eliciting an immune response to the pathogen encapsulated in a mucoadhesive controlled release particulate formulation comprising an open-celled polymeric foam of approximately 95% void volume, or particles thereof (see the specification at least at page 8, lines 5-6, 16-18 and 20; at page 11, lines 1-2; page 20, lines 10-11; page 10, lines 26-27; page 25, lines 17-20). Mucoadhesive polymers coatings are described at least page 25, lines 17-20, and enteric outer coatings or capsules, at least page 20, lines 28-31). The specification from page 1, line 23, until page 7, line 12 discloses

the pathogens listed in claim 9. The method of forming the composition as defined by claim 6 is known in the art and disclosed at least page 8, lines 5-13.

Rejection under 35 U.S.C. § 112, second paragraph

Claim 9 was rejected under 35 U.S.C. § 112 for being indefinite for reciting an improper Markush group. Claim 9 has been amended to correct the Markush group, replacing the list of diseases with the pathogens that cause them. Support for this amendment can be found at least at page 7, lines 9-12.

Rejections under 35 U.S.C. §102(b)

Claims 1, 3-5 and 8-11 were rejected under 35 U.S.C §102(b) as anticipated by O'Hagan. *J. Pharm. Pharmacol.*, 50(1):1-10 (1998) ("O'Hagan"). Claims 1, 3-5 and 8 were rejected under 35 U.S.C §102(b) as anticipated by Perez, et al., *J. Control Release*, 75:211-224 (2001) ("Perez"). Applicants respectfully traverse these rejections.

The Legal Standard

For a rejection of claims to be properly founded under 35 U.S.C. § 102, it must be established that a prior art reference discloses each and **every** element of the claims. *Hybritech Inc v Monoclonal Antibodies Inc*, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 US 947 (1987); *Scripps Clinic & Research Found v Genentech Inc*, 18 USPQ2d 1001 (Fed. Cir. 1991). The Federal Circuit held in *Scripps*, 18 USPQ2d at 1010:

Invalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference. *There must be no difference* between the claimed invention

and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention. (Emphasis added)

Analysis

None of O'Hagan or Perez recite all of the limitations of the claims as required by 35 U.S.C. §102(b). Neither O'Hagan nor Perez disclose a vaccine composition comprising a nucleic acid encoding an antigen eliciting an immune response to the pathogen encapsulated in a mucoadhesive controlled release particulate formulation comprising an open-celled polymeric foam of approximately 95% void volume or particles thereof, so the cited prior art cannot anticipate the claims.

Allowance of claims 1 and 3-11 is respectfully solicited.

Respectfully submitted,

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Date: January 4, 2006

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